



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

*SW*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,324	07/02/2002	Thomas V. Taylor	TAY-13	8280
23508	7590	10/22/2004		
LUNDEEN & DICKINSON, LLP PO BOX 131144 HOUSTON, TX 77219-1144			EXAMINER SNOW, BRUCE EDWARD	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/064,324

Applicant(s)

TAYLOR ET AL.

Examiner

Bruce E Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 13-63 is/are pending in the application.
- 4a) Of the above claim(s) 15,25,29-55 and 57-63 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 9 is/are allowed.
- 6) ☒ Claim(s) 8,13,14,18,21-24,27,28 and 56 is/are rejected.
- 7) ☒ Claim(s) 16,17,19,20 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

This application contains claims 29-63 are drawn to an invention nonelected with traverse in Paper No. 04272004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Response to Arguments*

Applicant's arguments filed 8/03/04 have been fully considered but they are not persuasive.

Regarding the rejection of claim 8 under 35 USC 101, applicant's argument is not persuasive. Claim 8 **positively claims**, not functionally claims, non-statutory subject matter.

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Taylor (6,558,429), applicant has added the language to claim 13, "*wherein the spikes are selectively retractable between a deployed and a retracted alignment with respect to the circumference*" and in claim 21 further describes the spikes are bendable between the two positions. The Examiner notes that this is merely functional language and the spike of Taylor are fully capable of being bent. It is noted that spikes 25 and extend radially out and are not taught being bent, however, are fully capable of being bent. Referring to spikes 71, they are deployed in an axial alignment and are bent in a generally radial alignment. See column 7, lines 52 et seq. There is no reason why the spikes cannot be

bent back retracting them to a deployed alignment, again, this is merely functional language.

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Bessler et al (5,855,601), it is the Examiner's position that the spikes are fully capable of the functional language, "*wherein the spikes are selectively retractable between a deployed and a retracted alignment with respect to the circumference*". Bessler et al teaches spikes 109, 104, 64 are portion of the stent member which is constructed from resilient materials; see column 6, lines 3 et seq. Because the spikes are resilient, they are capable of being compressed into a catheter and then expanding when removed from the catheter. Obviously the spikes can be re-compressed because they are formed from a resilient material. Additionally, the Examiner see no reason why the valve prosthesis can not fulfill the functional language and allow orthograde passage and inhibiting retrograde passage of gastric contents.

#### ***Election/Restrictions***

Applicant has amended claims 21-23 to depend from claim 18; these claims have been added back into prosecution.

Claims 15, 25, 29-55 and 57-63 remain withdrawn from consideration as being directed to a non-elected invention.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Regarding claim 8, the claimed invention is directed to non-statutory subject matter positively claiming the patient.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-14, 18, 21-24, 27-28, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor (6,558,429).

Taylor teaches an anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:

an annular body including element 13;

a valve 21 depending from the annular fixation body, the valve configured to allow orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and

a plurality of retractable spikes 25, 71 spaced along a circumference of the annular body adjacent one end thereof. Note column 6, lines 59 et seq. teaching the spikes are optionally barbed but are preferably not barbed where removal of the prosthesis is likely.

Claims 13-14, 18, 21-24, 27-28, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Bessler et al (5,855,601).

Bessler et al teaches an anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:

an annular body including element 21;

a valve 20 depending from the annular fixation body, the valve configured to allow orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and

a plurality of retractable spikes 64 spaced along a circumference of the annular body adjacent one end thereof.

The prosthesis of Bessler et al can be perorally implanted in the esophagus.

Claims 13-14, 18, 21-24, 27-28, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin, Jr. et al (6,676,698).

Referring to at least figures 35A-35B, McGuckin, Jr. et al teaches a valve comprising:

an annular body including element 400;

a valve 450 depending from the annular fixation body, the valve configured to allow orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and

a plurality of retractable spikes 451 spaced along a circumference of the annular body adjacent one end thereof.

#### ***Allowable Subject Matter***

Claims 1-7 and 9 are allowed.

Claims 16-17, 19-20, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

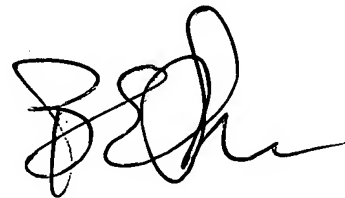
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to read 'BSN', with a stylized flourish extending to the right.

BRUCE SNOW  
PRIMARY EXAMINER